SUMMARY OF INTERVIEW

On Thursday 11 May 2006, an Applicant, Jay A. Lenker, was extended the courtesy of a telephone interview with the Examiner. A summary of the interview follows:

- There were no exhibits presented at the interview.
- During that interview, Claim 9 was discussed in detail. Baer '776 and Giba et al. '526 were the prior art cited primarily against Claim 9 and that prior art was reviewed.
- During the interview, Amendments to Claim 9 were proposed and reviewed. These Amendments included restrictions in the Claim language to include a bidirectional valve to distinguish against a one-way valve and the inclusion of the requirement that the valve be permanently attached to the drainage tube.
- Principal arguments pertaining to Claim 9 were directed toward the lack of prior art which discloses a trocar which is inserted through a pre-attached valve and the perceived lack of steering or deflection in the prior art to insert a chest drainage tube since chest drainage tubes are placed either during open surgery or percutaneously with the aid of a rigid, sharp trocar and a virtually straight, but somewhat dangerous, approach into the thoracic cavity.

Results of Interview

The Examiner suggested clarifications to the claims, such as requiring the valve to be a bidirectional valve and the permanent attachment of the valve to the proximal end of the chest drainage tube. The Examiner suggested that changes be made both in the Claims and in the Specification. Agreement was reached as to the general scope of the Claim amendments as well as corrections to the specification.

REMARKS

The foregoing amendments and the following comments are responsive to the objections and rejections set forth by the Examiner in the March 9, 2006 Office Action.

Claims 9-15 and 21-33 are pending in this application. The Examiner rejected Claims 9-15 and 21-33. In particular, the Examiner rejected Claims 9-15, 21-26, and 31 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,997,526 ("the Giba et al. patent") in view of U.S. Patent No. 5,419,776 ("the Baer patent"). The Examiner further rejected Claims 27-30 and 33 under 35 U.S.C. § 103(a) as being unpatentable over Giba et al. ('526), in view of Baer ('776) and further in view of U.S. Patent No. 5,897,531 ("the Amirana patent"). The Examiner rejected Claim 32 under 35 U.S.C. § 103(a) as being unpatentable over Giba et al. ('526), in view of Baer ('776) and further in view of Amirana ('531), and further in view of U.S. Patent No. 4,036,231 ("the Dodge patent"). In view of the following discussion, reconsideration of the application is respectfully requested.

REJECTION OF CLAIMS 9-15, 21-26, and 31 UNDER 35 U.S.C. § 103(a)

The Examiner rejected Claims 9-15, 21-26, and 31 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,997,526 ("the Giba et al. patent") in view of U.S. Patent No. 5,419,776 ("the Baer patent").

Claim 9

The Baer '776 patent appears not to disclose a valve that is permanently attached to the proximal end of a chest drainage tube. Baer valve does not appear to have a vacuum port for the purpose of opening or closing the valve and that is not in communication with the fluid chamber of the valve.

The Baer '776 Patent does not appear to disclose or teach a two way valve capable of permitting forward or reverse flow when the valve is open, but rather the valve only permits flow in the outward direction. No mention is made in the patent of a trocar or obturator which can be passed through the valve. Furthermore, the Baer '776 patent does not appear to disclose or teach a chest drainage apparatus that is steerable when advancing it into the thoracic cavity.

The Giba et al. '526 patent appears to disclose a conformable catheter capable of assuming a desired pre-programmed shape once it has been advanced to its target location. Giba et al. further teach the activation of the catheter into its pre-programmed shape by controls on the handle, which is located at the proximal end of the catheter.

The Giba et al. '526 patent does not appear to disclose or teach a steering apparatus that is capable of being movement back and forth, nor does the Giba et al. '525 patent appear to teach or disclose a trocar placed through the central lumen of the catheter which helps guide the catheter into the thoracic cavity.

Thus, Baer '776 and Giba et al. '526, alone or in combination, do not anticipate the use of a chest drainage apparatus that can be advanced into the thoracic cavity with a pre-attached non-removable valve, the use of a bidirectional valve, or the need or motivation for steering the apparatus during advancement.

In summary, there is no suggestion to pre-attach a valve to a chest drainage tube, there is no suggestion or motivation for use of a two-way or bidirectional valve, and there is no suggestion or motivation for steering the chest drainage tube into the thoracic cavity as taught in either Baer '776 or Giba et al. '526. There does not appear to be any motivation for combining Baer '776 and Giba et al. '526.

Because the references cited by the Examiner do not disclose, teach or suggest inserting a tapered tip of a flexible trocar and a distal end of an axially elongate tube into an incision into a thoracic cavity of a mammalian patient, wherein the flexible trocar is pre-inserted through a drainage lumen of a bidirectional, non-removable valve attached to a proximal end of the axially elongate tube and through a drainage lumen of the axially elongate tube and extends substantially the length of the axially elongate tube; selectively bending a region near the distal tip of the axially elongate tube while advancing the axially elongate tube into the thoracic cavity, wherein the bending steers the axially elongate tube into the thoracic cavity during insertion; removing the flexible trocar through the valve from the drainage lumen of the axially elongate tube and the drainage lumen of the valve; and selectively opening or closing the valve to control influx and efflux of fluid, air or contaminants into the thoracic cavity through the drainage lumen of the axially elongate tube, Applicants assert that Claim 9 is not obvious in view of Baer and Giba et al., alone or in combination. Applicants therefore

respectfully submits that Claim 9 is patentably distinguished over the cited references and Applicant respectfully requests allowance of Claim 9. No new matter has been added. Support for the bidirectionality of the valve is found in the drawings and original Claim 6. Support for the non-removability of the valve can be found in paragraph 16 of the specification.

Claims 10-15

Claims 10, 11, 12, 13, 14, and 15 which depend from Claim 9, are believed to be patentable for the same reasons articulated above with respect to Claim 9, and because of the additional features recited therein.

Claim 21

The Baer '776 Patent does not appear to disclose or teach a valve that is non-removable or permanently attached to the proximal end of the chest drainage tube. The disc, or valve occluder, appears to close the intake opening when exposed to reverse flow. No mention is made in the patent of a trocar or obturator which can be passed through the valve. Furthermore, the Baer '776 patent does not appear to disclose or teach a chest drainage apparatus that is steerable when advancing it into the thoracic cavity. The vacuum port of the Baer '776 patent appears not to control the opening or closing of the valve but is in flow communication with the flow chamber of the valve.

The Giba et al. '526 patent appears to disclose a conformable catheter capable of assuming a desired pre-programmed shape once it has been advanced to its target location. Giba et al. further teach the activation of the catheter into its pre-programmed shape by controls on the handle, which is located at the proximal end of the catheter.

The Giba et al. '526 patent does not appear to disclose or teach advancing a chest drainage apparatus over a guidewire, nor does the Giba et al. '525 patent appear to teach or disclose a trocar placed through the central lumen of the catheter, which helps guide the catheter into the thoracic cavity.

Thus, Baer '776 and Giba et al. '526, alone or in combination, do not anticipate the use of a chest drainage apparatus that can be advanced into the thoracic cavity

with a pre-attached non-removable valve, the use of a bidirectional valve, or the need or motivation for advancement over guidewire.

In summary, there is no suggestion to pre-attach a non-removable valve to a chest drainage tube, there is no suggestion or motivation for use of a two-way or bidirectional valve, and there is no suggestion or motivation for steering the chest drainage tube into the thoracic cavity over a guidewire as taught in either Baer '776 or Giba et al. '526. There does not appear to be any motivation for combining Baer '776 and Giba et al. '526.

Because the references cited by the Examiner do not disclose, teach or suggest inserting a hollow needle into an incision into the thoracic cavity of a patient; inserting a guidewire through the hollow needle into the thoracic cavity; removing the hollow needle after inserting the guidewire; pre-attaching a non-removable, bidirectional valve, further comprising a drainage lumen and a valve control lumen, to the proximal end of an axially elongate tube, wherein the axially elongate tube comprises a proximal end, a distal end, and a drainage lumen extending substantially the axial length of the axially elongate tube; inserting a flexible trocar comprising a tapered distal tip, and a guidewire lumen extending the length of the flexible trocar, through a drainage lumen of the valve, into the proximal end of the axially elongate tube and into the drainage lumen of the axially elongate tube until the tapered distal tip extends beyond the distal end of the axially elongate tube; inserting a distal end of the axially elongate tube, comprising the pre-inserted flexible trocar and pre-attached bidirectional valve, over the guidewire and through the incision into the thoracic cavity of the patient, wherein the distal end of the axially elongate tube is advanced into the thoracic cavity of the patient; removing the flexible trocar from the drainage lumen of the axially elongate tube and from the drainage lumen of the valve; selectively opening or closing the drainage lumen of the valve, to control the influx and efflux of fluid, air or contaminants into the thoracic cavity through the drainage lumen of the axially elongate tube; and removing the guidewire after inserting the axially elongate tube, Applicants assert that Claim 21 is not obvious in view of Baer and Giba et al., alone or in combination. Applicants therefore respectfully submits that Claim 21 is patentably distinguished over the cited references and Applicant respectfully requests allowance of Claim 21.

Claims 22-33

Claim 28 has been canceled. Claims 22, 23, 24, 25, 26, 27, 29, 30, 31, 32, and 33, which depend from Claim 21, are believed to be patentable for the same reasons articulated above with respect to Claim 21, and because of the additional features recited therein.

NEW CLAIMS

New Claims 34, 35, and 36 have been added to more fully define the Applicant's invention. No new matter has been added.

AMENDMENTS TO THE SPECIFICATION

The specification has been amended to include the word bidirectional in front of certain embodiments of the valve. Support for the bidirectional, or two-way, nature of the valve is found in Figures 1, 3B, 5A, 5B, and 5C, which show a valve that opens or closes its lumen thus prohibiting or allowing flow without regard to which direction the flow is moving. Further support for bidirectionality of the valve can be found in original Claim 6 which states that the apparatus comprises "a valve, wherein an efflux or an influx of fluid, air or contaminants is selectively controlled out of or into the body cavity through the drainage lumen of said axially elongate tube.

CONCLUSION

In view of the forgoing, the present application is believed to be in condition for allowance, and such allowance is respectfully requested. If further issues remain to be resolved, the Examiner is cordially invited to contact the undersigned such that any remaining issues may be promptly resolved.

Respectfully submitted,

Dated: 5 June 2006

By: Jay A Lenker

Jay A. Lenker
(949) 494-3645